IN THE UNITED STATES COURT OF FEDERAL CLAIMS

GILEAD SCIENCES, INC.,
Plaintiff,

v.

THE UNITED STATES OF AMERICA,
Defendant,

20-cv-499C

Senior Judge Charles F. Lettow

UNITED STATES' MOTION TO DISMISS

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INTRODUCTION

Gilead Sciences, Inc. (Gilead) brings this action against the United States of America (Government) in response to the Government's currently-pending patent suit against Gilead. In November 2019, the Government sued Gilead in the District of Delaware (Delaware Litigation) alleging willful infringement of four patents held by the Department of Health and Human Services (HHS) covering innovative pre-exposure prophylaxis (PrEP) regimens that protect against HIV-1 transmission.[1] Use of Gilead's products Truvada® and Descovy® for PrEP infringe these patents, yet for years Gilead has refused to license the patents and instead challenged (unsuccessfully) the validity of these publicly-funded inventions at the Patent and Trademark Office (PTO).[2] Accordingly, in the Delaware Litigation, the Government is seeking money damages for Gilead's infringement, which continues to generate billions of dollars in annual revenue for the company.

Gilead's ill-conceived suit attempts to open another front in this litigation but (i) lacks a proper jurisdictional basis, (ii) seeks damages already sought in the Delaware Litigation, and (iii) otherwise fails to state proper contract claims. Most notably, because the Complaint asserts breach of contract claims more than a decade after the alleged breaches occurred, the claims are clearly barred by the six-year limitations period of 28 U.S.C. § 2501. Similarly, Gilead's breach of contract claims in this Court are also barred by 28 U.S.C. § 1500 because they are based on the same allegations as an affirmative defense it has asserted in Delaware. Specifically, the contracts at issue in this case, four Material Transfer Agreements and a subsequent Clinical Trial Agreement,

[1] *United States v. Gilead Sciences, Inc., et al.*, C.A. No. 1:19-cv-1203-MN (D. Del) (Delaware Litigation).

[2] Gilead has previously brought *Inter Partes* Review petitions against each of the patents asserted by the United States. The Patent Trial and Appeal Board denied all four petitions.

are also alleged to have been breached on the exact same facts pled for Gilead's "unclean hands" affirmative defense in the Delaware Litigation.

Gilead's damages claims fare no better. Gilead seeks attorneys' fees for defending itself against the patent infringement allegations, while seeking the same fees in Delaware, a novel theory that lacks a waiver of sovereign immunity. Gilead also seeks damages for reputational harm resulting *from* the Delaware Litigation, a speculative tort-based theory of relief that is expressly barred in this Court. Both theories of damages therefore lack a jurisdictional basis. Additionally, Gilead has failed to adequately plead causation or actual damages resulting from the alleged breaches. Its requested attorneys' fees bear a tenuous relationship to the alleged breach, and Gilead vaguely claims reputational damages due to the Delaware Litigation, not the alleged breaches of contract.

In short, Gilead's Complaint is improper for multiple jurisdictional reasons and, alternatively, for failing to state legally sufficient damages claims. Accordingly, it should be dismissed under Rule 12(b)(1) and/or 12(b)(6).

I. QUESTIONS PRESENTED

1) Whether Gilead's Complaint is barred by 28 U.S.C. § 2501, as the alleged breach of contract accrued in 2006, over six years before Gilead brought this action?
2) Whether Gilead's claims for attorneys' fees resulting from the Delaware Litigation are jurisdictionally barred as seeking consequential damages and a double recovery?
3) Whether Gilead's damages claims for reputational harm resulting from the Delaware Litigation sound in tort and are expressly barred by 28 U.S.C. § 1491?
4) Whether Gilead is barred by 28 U.S.C. § 1500 from bringing this action, as Gilead has already asserted an affirmative defense in the Delaware Litigation for the same breaches of contract alleged in this action?

5) Whether Gilead failed to plead a claim upon which relief may be granted with regard to its cursory damages claims for attorneys' fees and reputational harm?

II. STATEMENT OF FACTS

A. Under Terms of the MTAs, Gilead Supplied Study Drugs for CDC Research and CDC Owned All Resulting Patents

Gilead's claims chiefly relate to four Material Transfer Agreements (MTAs) it signed with the Centers for Disease Control and Prevention (CDC) in the early 2000s. Dkt. Nos. 1-4, 1-5, 1-6, 1-7. Under the MTAs, Gilead provided drugs for CDC's use in federally-funded HIV-prevention research. Some of that research led to innovative regimens for the prevention of HIV transmission in at-risk populations known as pre-exposure prophylaxis (PrEP). As permitted by the MTAs, the Government applied for and received patents covering these innovative regimens. The Government filed Provisional Patent Application No. 60/764,811 (the '811 Provisional) covering its PrEP regimens in February 2006, followed by the first non-provisional Application No. 11/649,557 (the '547 Application) on January 31, 2007. The '547 Application published as U.S. Patent Publication No. 2007/0265227 on November 15, 2007 and issued as a patent in 2015. *See* Exs. 5–8 (cover pages). The Government applied for and received three additional patents covering these innovative PrEP regimens. *See* Dkt. No. 1 at 3 (¶ 11); *see generally* Ex. 1.[3] All four HHS Patents asserted in the Delaware Litigation (Patents-in-Suit) claim priority to the '547 Application, and, in turn, the '811 Provisional. Exs. 5–8 (identifying priority on cover page of each patent).

[3] For the Court's convenience, all relevant documents from the Delaware Litigation are attached as Exhibits to this Motion. *See* Ex. 1 (United States' Complaint), Ex. 2 (Gilead's original Answer and Counterclaims), Ex. 3 (Gilead's First Amended Answer and Counterclaims), and Ex. 4 (Gilead's Second Amended Answer and Counterclaims).

As disclosed and claimed by the Patents-in-Suit, PrEP involves taking a preventative, two-drug regimen of tenofovir disproxil fumarate (TDF) or another tenofovir ester, like tenofovir alfenamide (TAF), in combination with emtricitabine (FTC). Gilead's Truvada® product contains both TDF and FTC. Gilead's Descovy® product contains both TAF and FTC. Both products were originally developed for HIV treatment and are now, following CDC's innovative research, approved for use as PrEP. Ex. 1 at 10–12 (¶¶ 47–57).

The MTAs contain uniform provisions that direct ownership of all intellectual property resulting from CDC research to the federal government, and, in turn, provide that CDC would "give serious and reasonable consideration" to Gilead's request for a license to any inventions that resulted from the research.[4] *See, e.g.*, Dkt. No. 1-4 at ¶ 8. Thus, it was always understood that the Government would own any patents resulting from MTA-related research, and would consider offering Gilead a license, which it did. As detailed in the Delaware Litigation Complaint, as the first HHS patent approached issuance, the Government repeatedly offered Gilead a license and Gilead repeatedly refused. Ex. 1 at 57–59 (¶¶ 233–43).

B. Gilead Claims Breaches of MTAs Due to an Alleged Lack of Notification of Inventions Publicly Disclosed by CDC

The MTAs also indicate that CDC would "promptly notify" Gilead of "any inventions" resulting from the research, and that CDC "assumes liability [under the MTAs] only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. § 2671 *et seq.*" *E.g.*, Dkt. No. 1-4 at ¶ 8. Gilead claims breaches of the MTAs based solely on alleged failures by CDC to provide "prompt" notification of inventions. *See* Dkt. No. 1 at 4 (¶ 13). Gilead alleges that the Government's "contractually required notice" under the MTAs should have occurred "more than eight years"

[4] The Government has repeatedly offered Gilead a license, and Gilead has repeatedly refused to take one.

before October 2014, i.e., on or around February 3, 2006, when CDC filed the '811 Provisional. *Id*. at 3-4 (¶¶ 13, 11). But, as discussed, the '574 Application became publicly available in 2007, and Gilead admits that CDC published the patented research in 2008 with a statement that it was the subject of a patent application. *Id.* at 21 (¶ 76).

C. The Patented CDC Work Predated and Informed the Clinical Trial Addressed by the CTA

Gilead's claim for breach of the Clinical Trial Agreement differs. The original CTA, executed in 2004, provided that Gilead would again supply drugs to CDC for use in a federal clinical trial of TDF-only PrEP in Botswana. *Id*. at 15 (¶ 50). It also provided that CDC would "not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." *Id*. at 15 (¶ 52). Gilead, in turn, alleges that "[h]ad CDC fulfilled its contractual obligations under the CTA to not seek patent protection on alleged inventions derived from the Botswana trial, the HHS Patents never would have issued." *Id*. at 6 (¶ 21).

But when the results from this trial were published, the clinical researchers made clear that, after the original CTA was executed, the regimen was switched from a single-drug, TDF-only regimen (known as the TDF1 study) to a TDF-FTC dual-drug regimen (known as the TDF2 study) in response to the earlier CDC work performed under the MTAs.[5] In other words, the Government did not seek patent protection for inventions derived from the TDF2 study. Instead, the change to the TDF2 (Truvada®) regimen—claimed in the Patents-in-Suit—was the result of the inventions the Government was already in the process of patenting. The resulting publication verifies this, stating: "When data from [the CDC researcher's] studies in animals [] showed the superior

[5] While the Government concedes that the patented CDC research was conducted with drugs obtained through MTAs asserted by Gilead, it does not concede that all MTAs asserted by Gilead related to the patented research or provided drugs for that research.

efficacy of TDF–FTC, [the Botswana researchers] changed the active drug to TDF–FTC (TDF2 study)." Dkt. No. 1-15 at 2 (emphasis added). Indeed, the "TDF2" moniker for the trial was adopted in response to this 2007 drug-protocol change.[6]

While subsequent amendments to the CTA did provide for Truvada® to be provided, Dkt. No. 1 at 16 (¶¶ 55–56), they were all executed after CDC's filing of its first patent application (the '811 Provisional).[7] Rather than demonstrating an invention derived from the TDF2 trial, the CTA amendments show how the earlier CDC innovations claimed in the Patents-in-Suit informed the TDF2 drug protocol.[8] Simply put, no patented inventions at issue in the Delaware Litigation were derived from the TDF2 trial.

D. Gilead Raises the Same Breach of Contract Issues Already Raised in the Delaware Litigation

Gilead admits that it brings this action only "because the Government is asserting patents," Dkt. No. 1 at 1 (¶ 2), against it in the Delaware Litigation. Ex. 1. And it previously raised the same breach of contract allegations in Delaware as part of an unclean hands defense in its original Answer and Counterclaims. Specifically, Gilead alleged that the "Government breached its obligations under at least four Material Transfer Agreements by failing to provide GSI with prompt

[6] "Beginning on February 20, 2007, a total of 18 participants in the TDF1 study enrolled in the TDF2 study and continued to receive the study medication as previously assigned (i.e., active drug or placebo)." *Id.*

[7] Gilead admits that it did not enter into the first CTA amendment until October 3, 2006 and that this amendment "modified the study drug to be supplied for the Botswana clinical trial described in the original CTA from TDF to Truvada® tablets." *Id.* at 15-16 (¶¶ 54–55).

[8] Gilead pleads that decisions made in the prosecution of the HHS Patents "derive from the trials described in the original CTA and its subsequent amendments." Dkt. No. 1 at 22 (¶ 78) (emphasis added). But this ignores that (1) the original CTA applied to the single-drug protocol (not changed until 2007) and (2) that the animal studies that underlie CDC's patented research accurately predicted the high efficacy of PrEP seen in later human trials. Ex. 1 at 44 (at ¶ 168).

notice of the alleged inventions or the patent applications that resulted in the Patents-in-Suit." Ex. 2 at 66 (¶ 5). Gilead further alleged that "[d]ue to the Government's failure to provide prompt notice to [Gilead, it was] . . . denied the opportunity to make the Government aware of pertinent prior art that was not presented during the examination of one or more of the Patents-in-Suit, or to indicate the role of [Gilead] scientists in the work that led to the alleged inventions." *Id*. Gilead also alleged that "the Government has also demonstrated unclean hands through its encouragement of both the public use and the prescription of Truvada® for PrEP purposes . . . ." *Id*. (¶ 6). Based on these allegations, Gilead asserted four counterclaims seeking a declaratory judgment of patent unenforceability based explicitly on the "Government's unclean hands following from the Government's breach of the MTAs." *Id*. at 89 (¶ 89), 91 (¶ 107), 93 (¶ 125), 95 (¶ 143). Gilead also pled a similar affirmative defense. *See id*. at 66–67 (¶¶ 4–6).

Less than one month before filing this suit, Gilead amended its Answer and Counterclaims, removing the counterclaims explicitly directed to breach of contract, and shifting much of the supporting allegations into its "unclean hands" affirmative defense. *Compare* Ex. 2 at 66 (¶ 5–6) *with* Ex. 3 at 67–77 (¶ 4–42). It also added a similar defense relating to the CTA. *Id*. at 68 (¶6). Gilead further alleged, in its waiver defense, that "[t]he Government's failure to provide [] notice [of its patent applications] violated the terms of several MTAs between [Gilead] and the CDC." *Id*. at 85 (¶ 73). These pleadings were pending at the time Gilead's Complaint was filed in this Court.

Gilead later amended its Answer and Counterclaims a second time, adding the allegation (to its unclean hands defense) that the "Government has engaged in affirmative misconduct" by "obtaining the HHS Patents in breach of the MTAs and CTA." Ex. 4 at 77 (¶ 43). It added a similar allegation to its "failure to mitigate" defense. *Id*. at 89 (¶ 84). This is the current pleading

pending in the Delaware Litigation. In response, the Government has filed a Motion to Strike all of Gilead's equitable affirmative defenses on sovereign immunity grounds. While briefing is complete, and argument scheduled for October 30, 2020, that motion remains pending.

In its Complaint in this Court, Gilead asserts five counts of breach of contract (based on the same four MTAs and the CTA). Dkt. No. 1 at 31–37 (¶¶ 111–46). For each claim, Gilead demands monetary relief resulting from "unnecessary attorneys' fees" and "reputational harm." *Id*. at 32–36 (¶¶ 117, 123, 131, 138, 146). Gilead alleges that the requested attorneys' fees are those incurred in "investigating the Government's claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute, in an amount over $10,000." *Id*. Gilead also seeks the same attorneys' fees in the Delaware Litigation under 35 U.S.C. § 285. Ex. 4 at 110.

With regard to "reputational harm," Gilead simply alleges that it has "suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial." *E.g.*, Dkt. No. 1 at 32 (¶ 117). But the Complaint offers no details of any defamatory (or otherwise) improper acts by the Government in the Delaware Litigation—or any resulting "harm." *Id.*

III. ARGUMENT

A. Gilead's Claims Are Untimely and Jurisdictionally Barred by 28 U.S.C. § 2501 as the Alleged Breach Is Pled to Have Occurred in 2006

1. Gilead Bears Burden of Establishing Jurisdiction

For a motion under Rule 12(b)(1) of the Rules of the Court of Federal Claims (RCFC), the Court construes the undisputed factual allegations in the light most favorable to the plaintiff. *See McDonald v. United States*, 37 Fed. Cl. 110, 113 (1997); *Lewis v. United States*, 32 Fed. Cl. 59, 62 (1994). Gilead, however, bears the burden of establishing jurisdiction. *See, e.g.*, *Acevedo v. United States*, 824 F.3d 1365, 1368 (Fed. Cir. 2016); *Entines v. United States*, 39 Fed. Cl. 673,

678 (1997). In other words, it must show that the Court has had jurisdiction from the case's inception and at all times thereafter. *See Sheridan v. United States*, 120 Fed. Cl. 127, 129 (2015) (citing *Hardie v. United States*, 367 F.3d 1288, 1290 (Fed. Cir. 2004)). While Gilead's factual allegations must only rise above a speculative level, the Court is not required to accept Gilead's legal conclusions, even when seemingly presented as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 564 (2007).

2. Under 28 U.S.C. § 2501, Gilead's Claims Are Subject to a Six-Year Statute of Limitations

Gilead alleges jurisdiction "under the Tucker Act, 28 U.S.C. § 1491(a)(1), because this action involves claims for damages greater than $10,000 . . . founded upon express contracts with the Government." Dkt. No. 1 at 7 (¶ 25). But a claim must fall within the six-year statute of limitations set forth in 28 U.S.C. § 2501. This limitations period is jurisdictional and cannot be waived. *See John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 133–34 (2008). Nor can the six-year period be tolled, equitably or otherwise. *Blodgett v. United States*, 792 F. App'x 921, 926 (Fed. Cir. 2019) (citing *FloorPro, Inc. v. United States*, 680 F.3d 1377, 1382 (Fed. Cir. 2012)) Rather, it must be strictly construed and exceptions are not to be implied. *See Soriano v. United States*, 352 U.S. 270, 276 (1957).

3. Contract Claims under 28 U.S.C. § 1491 Accrue at the Time of the Alleged Breach

Under section 2501, a breach-of-contract claim against the United States first accrues on the date when all the events have occurred which fix the liability of the government and entitle the claimant to institute the action. *Kinsey v. United States*, 852 F.2d 556, 557 (Fed. Cir. 1988); *see also Brighton Village Assocs. v. United States*, 52 F.3d 1059, 1060 (Fed. Cir. 1995). Even if the claimant claims ignorance of this first accrual, the limitations period continues to run when the

operative facts exist and are not inherently unknowable. *See, e.g.*, *Menominee Tribe v. United States*, 726 F.2d 718, 720–22 (Fed. Cir. 1984).

Though this Court recognizes an "accrual suspension doctrine," this doctrine suspends accrual only until a claimant knows or should have known that the claim existed. *See, e.g.*, *Alliance of Descendants of Tex. Land Grants v. United States*, 37 F.3d 1478, 1482 (Fed. Cir. 1994); *Welcker v. United States*, 752 F.2d 1577, 1580 (Fed. Cir. 1985). Moreover, the doctrine is "'strictly and narrowly applied,'" and applies only in very limited circumstances where the plaintiff proves "that defendant has concealed its acts . . . or . . . that its injury was 'inherently unknowable' at the accrual date." *See Martinez v. United States*, 333 F.3d 1295, 1319 (Fed. Cir. 2003) (quoting *Welcker*, 752 F.2d at 1580). This burden cannot be met, however, where the Government's actions are "open and notorious." In that case, "[the] plaintiff is on inquiry as to its possible injury. . . . [and] the statute of limitations begins to run."[9] *Jakoby v. United States*, 38 Fed. Cl. 192, 195 (1997) (quoting *Catellus Dev. Corp. v. United States*, 31 Fed. Cl. 399, 405 (1994)); *see also Coastal Petroleum Corp. v. United States*, 228 Ct. Cl. 864, 867 (1981).

4. Gilead's Claims Accrued Outside of the Six Year Statute of Limitations

Gilead alleges that the "contractually required notice" under the MTAs should have occurred "more than eight years" before October 2014, *i.e.*, on or around February 2006, when CDC filed its provisional patent application. Dkt. No. 1 at 3–4 (¶¶ 11, 13). Thus, Gilead's claim, first accrued in 2006, as "all the events [had] occurred which fix[ed] the liability of the Government." *Kinsey*, 852 F.2d at 557. Accordingly, Gilead's claimed breaches of the MTAs all

[9] Accordingly, this doctrine is evaluated by an objective standard, so "a plaintiff does not have to possess actual knowledge of all the relevant facts in order for the cause of action to [nonetheless] accrue." *Fallini v. United States*, 56 F.3d 1378, 1380 (Fed. Cir. 1995).

accrued more than six years before Gilead filed its Complaint and therefore are jurisdictionally barred by section 2501.

Gilead similarly alleges that the Government breached the CTA when it "filed the '811 Provisional or the '574 Application in direct contravention of the terms of the CTA . . . ." Dkt. No. 1 at 22 (¶ 79). In other words, as with the MTAs, Gilead's claim accrued when CDC filed its provisional application in 2006. Therefore, the alleged breach of the CTA also accrued more than six years prior to the filing of its Complaint and is jurisdictionally barred.

5. Gilead Cannot Invoke the Accrual Suspension Doctrine

There is also no basis for Gilead to invoke the accrual suspension doctrine. The non-provisional application that matured into the first of the Patents-in-Suit was filed on January 31, 2007, and published by the PTO on November 15, 2007. *See* Ex. 5 at 1. An international patent application disclosing the same subject matter was published on August 16, 2007. *See* Ex. 1 at 33 (¶ 129) (citing PCT Application No. US2007/002926). Moreover, a scientific article discussing the patented research was published in 2008. *See* Dkt. No. 1-20. It included a listing entitled "Competing Interests," which discloses that several CDC authors "are named in a U.S. Government patent application related to methods for HIV prophylaxis." *Id.* at 1. Gilead further admits that, on February 1, 2008, Dr. Walid Heneine, a CDC researcher and named inventor of the HHS Patents, emailed a draft of the article (including the "Competing Interests" section) directly to Gilead. Dkt. No. 1 at 21 (¶ 76).

Thus, the Government's actions in applying for its patents were "open and notorious" and Gilead was "on inquiry as to its possible injury." *Jakoby*, 38 Fed. Cl. at 195. Publicly disclosed Government acts cannot be a "concealment" that suspends the statute of limitations. *See Japanese War Notes Claimants Ass'n of the Philippines v. United States*, 373 F.2d 356, 359 (Ct. Cl. 1967) ("Ignorance of rights which should be known is not enough.").

Gilead pleads that the alleged breaches began by 2007, roughly the same time period when Gilead should have known, through direct communications from CDC and/or publicly available information, about the filing of the patent applications. Thus, even assuming a breach occurred, the limitations period expired by 2014 at the latest, based on an objective analysis of first accrual and the availability of sufficient public information to put Gilead on notice.

6. Gilead Cannot Invoke the Continuing Claim Doctrine

Under the "continuing claims" doctrine, there are circumstances when later arising claims may be heard "even if the statute of limitations has lapsed for earlier events." *Tamerlane, Ltd. v. United States*, 550 F.3d 1135, 1144–45 (Fed. Cir. 2008). But "[i]n order for the continuing claim doctrine to apply, the plaintiff's claim must be inherently susceptible to being broken down into a series of independent and distinct events or wrongs, each having its own associated damages." *Brown Parks Estates-Fairfield Dev. Co. v. United States*, 127 F.3d 1449, 1456 (Fed. Cir. 1997). "[A] claim based upon a single distinct event, which may have continued ill effects later on, is not a continuing claim." *Id.* Likewise, the doctrine does not apply where a single event produces "ill effects that continue to accumulate over time." *See Ariadne Fin. Servs. Pty. Ltd. v. United States*, 133 F.3d 874, 879 (Fed. Cir. 1998).

Gilead's breach of contract allegations fall into the "single event" category. Gilead's allegations center on an alleged Government failure to notify Gilead of the inventions at the time it filed the '811 Provisional or '547 Application. Dkt. No. 1 at 3–4 (¶¶ 11–13), 22 (¶ 79). Since that time, Gilead alleges its damages have accumulated, asserting that "has suffered, and will continue to suffer, damages because of the Government's breaches of the MTAs and the CTA." *Id.* at 4 (¶ 14). The alleged failure to notify Gilead is thus a "single distinct event" and is not inherently susceptible to being broken down into a "series of independent and distinct events."

Moreover, even were Gilead to have pleaded continuing breaches, Gilead's damages will be limited to breaches from a very short time span—from April 2014 (six years prior to Gilead's Complaint) through October 2014 (the latest date by which Gilead concedes notice was given, Dkt. No. 1 at 23–25 (¶¶ 83–86)). And there is no pleading by Gilead of independent and distinct breaches in the Complaint for this time period.

B. Gilead's Demand for Attorneys' Fees Seeks an Impermissible Double Recovery

Separately and independently from the statute of limitations, Gilead seeks improper and barred relief for the alleged breaches of the MTAs and CTA. Gilead's claim for attorneys' fees is specifically barred because it seeks identical relief to the relief it seeks in the Delaware Litigation. The law is clear—"double recovery for the same injury is inappropriate." *Aero Prods. Int'l, Inc. v. Intex Recreation Corp.*, 466 F.3d 1000, 1017 (Fed. Cir. 2006); *EEOC v. Waffle House, Inc.*, 534 U.S. 279, 297 (2002). This bar "applies even where claims exist under both contract and tort, or where a claim exists under a statutory provision and under common law." *S. Cal. Fed. Sav. & Loan Ass'n v. United States*, 422 F.3d 1319, 1333 (Fed. Cir. 2005).

There is no question that the relief Gilead seeks in this Court and the District of Delaware is identical. Gilead has asked the Delaware court to "[d]eclare that this is an exceptional case" and "award [] its reasonable attorneys' fees pursuant to 35 U.S.C. § 285." Ex. 4 at 110 (¶ (e)). In this Court, Gilead seeks recovery of "unnecessary attorneys' fees, including but not limited to investigating the Government's claims, defending itself against meritless claims of patent infringement in the Delaware Litigation, and negotiating with CDC over the dispute." Dkt. No. 1 at 32 (¶ 117). Both pleadings seek the same relief (attorneys' fees), and that relief flows from the same operative facts (the Government's patent infringement suit in the District of Delaware). Accordingly, this is clearly "impermissible double recovery." *Tex. Advanced Optoelectronic Sols.*,

Inc. v. Renesas Elecs. Am., Inc., 895 F.3d 1304, 1328 (Fed. Cir. 2018) (quoting *Aero Prods.*, 466 F.3d at 1017).[10]

Additionally, "statutory schemes with their own remedial framework exclude alternative relief under the general terms of the Tucker Act." *United States v. Bormes*, 568 U.S. 6, 13 (2012). The Federal Circuit "has drawn the same conclusion in several cases, recognizing that when such a specific and comprehensive scheme for administrative and judicial review is provided by Congress, the Court of Federal Claims' Tucker Act jurisdiction over the subject matter covered by the scheme is preempted." *Alpine PCS, Inc. v. United States*, 878 F.3d 1086, 1092–93 (Fed. Cir. 2018) (quotations and citations omitted). Because Gilead's claim for attorneys' fees in the Delaware Litigation are covered by the standard for exceptional cases in 35 U.S.C. § 285, the general terms of the Tucker Act do not confer jurisdiction here.

Likewise, there is also no waiver of sovereign immunity sufficient to sustain Gilead's claim to attorneys' fees in this Court. The general rule in American courts, known as the "American Rule," is that each party must pay its own attorneys' fees. *See Alyeska Pipeline Serv. Co. v. Wilderness Soc'y*, 421 U.S. 240, 247 (1975). For Tucker Act claims, the only statute authorizing attorneys' fees awards against the United States is the Equal Access to Justice Act (EAJA), 28 U.S.C. § 2412. And the EAJA statute makes clear that a plaintiff can only recover such fees from the Government "in a civil action . . . brought by or against the United States in any court <u>having jurisdiction of that action</u> . . . ." *Id.* § 2412(d)(1)(A). Therefore, this Court cannot award fees resulting from the Delaware Litigation, for which is no jurisdiction. *See Burkhardt v. Gober*, 232 F.3d 1363, 1367 (Fed. Cir. 2000) (holding that the language "'having jurisdiction of that action,'

[10] To the extent that Gilead argues that double recovery concerns are premature and should only be resolved if and when Gilead prevails on its section 285 claim in Delaware, such an argument simply demonstrates the duplicative nature of its suit.

is plain, clear, and unambiguous").[11] Without any waiver provision, including EAJA, the Government is immune from suit for attorneys' fees in this action. *See United States v. Mitchell*, 445 U.S. 535, 538 (1980).

C. Gilead's Demand for Attorneys' Fees Seeks Unrecoverable Consequential Damages

As a general rule, damages for breach of contract are recoverable in this Court if they are 1) proximately caused by the breach; 2) reasonably calculable, *see Neely v. United States*, 152 Ct. Cl. 137, 146 (1961); and 3) foreseeable at the time of contract. *Prudential Ins. Co. of Am. v. United States*, 801 F.2d 1295, 1297 (Fed. Cir. 1986). Remote, unforeseeable, or consequential damages are not recoverable. *Mendenhall v. United States*, 20 Cl. Ct. 78, 85 (1990); *Begay v. United States*, 16 Cl. Ct. 107, 134 (1987); *N. Helex Co. v. United States*, 524 F.2d 707, 720 (1975). For consequential damages, this Court looks to "whether the damages plaintiff seeks are the 'natural and probable consequences' of the alleged breach of the [] agreement, i.e., whether the damages were within the contemplation of the parties at the time the contract was made." *Smokey Bear v. United States*, 31 Fed. Cl. 805, 809 (1994) (quoting *Prudential Ins. Co. v. United States*, 801 F.2d 1295, 1300 (Fed. Cir. 1986)).

Gilead's claim of "unnecessary attorneys' fees," Dkt. No. 1 at 32 (¶ 117), clearly seeks consequential damages in response to alleged breaches of the MTAs and CTA. This Court has long prohibited the award of litigation fees and costs as damages for breach of contract. In *Kania v. United States*, 227 Ct. Cl. 458 (1981), for example, where the plaintiff sought litigation costs and fees incurred in defending a criminal indictment, the Court of Claims found that "[i]t is the

[11] Further, Gilead would not meet the eligibility requirements set forth in 28 U.S.C. § 2412(d)(2)(B).

kind of consequential damages not normally awarded in contract breach cases." *Id.* at 467.[12] The Court further stated that "[c]ourts do not, in awarding breach damages, follow through the remote indirect consequences of the breach as distinguished from those directly in contemplation when the contract was made." *Id.*; *see also Albermarle Bank & Trust Co. v. United States*, 12 Cl. Ct. 704, 706–707 (Cl. Ct. 1987) (relying on *Kania* in rejecting claim for attorneys' fees incurred as result of Government litigation).

Gilead's claim for attorneys' fees can, thus, be dismissed as seeking consequential damages. While Gilead states that its claims for attorneys' fees are a "direct and proximate result" of this alleged breach, Dkt. No. 1 at 32 (¶ 117), its Complaint belies this assertion. Gilead's alleged breaches center on CDC's alleged failure to "promptly notify" Gilead of any inventions arising out under the MTAs and allegedly violating the terms of the CTA by "not only filing patent applications" but also by failing "to disclose to Gilead the purported invention(s)" in its applications. Dkt. No. 1 at 4 (¶ 13); *see also id.* at 5–6, 31–36 (¶¶ 19, 20, 21, 110, 115, 116, 121, 122, 129, 130, 136, 137, 145).

In turn, Gilead claims fees for "investigating the Government's claims" "defending" itself in the Delaware Litigation and "negotiating with CDC."[13] *Id.* Thus, Gilead's claim of attorneys' fees arises from alleged Government actions spanning more than a decade in (i) not disclosing its invention, (ii) secretly filing patent applications on those inventions, (iii) obtaining issuance of the HHS Patents, and most importantly, (iv) bringing suit in the Delaware Litigation, which is at the

[12] The Court also found that no contract "sufficient to satisfy this court's jurisdictional requirements" existed. *Id.* at 467.

[13] More specifically, Gilead pleads that the "unnecessary attorneys' fees" are the result, at least in part, of (i) "the Government's delay in notifying Gilead of its purported invention," (ii) "the issuance of the '509 Patent on June 2, 2015," and (iii) "the Government's demands that Gilead license the '509 Patent beginning on March 11, 2016." *Id.*

heart of Gilead's claims to fees. Thus, the claim for attorneys' fees is very distant from the years-earlier alleged breaches of contract and any asserted connection is conclusory at best.

Accordingly, the attorneys' fees that Gilead seeks are not the "natural and probable consequence" of the alleged breaches and were certainly not "within the contemplation of the parties at the time the contract[s were] made." *Smokey Bear* 31 Fed. Cl. at 809 (internal quotation omitted). Such remote breaches are not the proximate cause of the damages Gilead seeks, and those damages would not have been foreseeable when the MTAs and CTA were executed, especially since the MTA provisions foresaw and anticipated Gilead could take a future license to the HHS Patents (something it repeatedly refused to do).

D. Gilead's Demand for Reputational Damages Sounds in Tort

Jurisdiction in this Court is limited to claims "not sounding in tort." 28 U.S.C. § 1491(a)(1). Under the Tucker Act, there can be a 'tortious' breach of contract, but not a tort independent of the contract. *L'Enfant Plaza Props., Inc. v. United States*, 645 F.2d 886, 892 (Ct. Cl. 1981). In other words, there must be a direct connection between the contractual obligations at issue and the alleged tortious conduct. *H.H.O., Inc. v. United States*, 7 Cl. Ct. 703, 706–707 (Ct. Cl. 1985); *see also Aleutco Corp. v. United States*, 244 F.2d 674, 678–9 (3d Cir. 1957). "The mere labeling of a claim as one sounding in contract does not make it a contract claim." *Colon v. United States*, 35 Fed. Cl. 337, 343 (1996); *see also Adams* v. *United States*, 20 Cl. Ct. 132, 135 (1990). Thus, this Court must determine whether an alleged contract claim actually sounds in tort. *See Morris v. United States*, 33 Fed. Cl. 733, 742 (1995); *Dakota Tribal Indus. v. United States*, 34 Fed. Cl. 295, 297 (1995). If it does, the Court lacks jurisdiction over the claim.

Gilead pleads that it "has suffered reputational harm due to the Delaware Litigation in an amount to be determined at trial." *E.g.*, Dkt. No. 1 at 32 (¶ 117). But "[l]oss of business reputation is not a compensable damage claim because it sounds . . . in tort and is speculative." *Lucas v.*

United States, 25 Cl. Ct. 298, 310–311 (1992) (citing *Essen Mall Props. v. United States*, 21 Cl. Ct. 430, 447 (1990)); *Frawley v. United States*, 14 Cl. Ct. 766, 767 (1988); *Pinkston v. United States*, 6 Cl. Ct. 263, 267 (1984); *Berdick v. United States*, 612 F.2d 533, 536 (1979); *Somali Dev. Bank v. United States*, 508 F.2d 817, 821 (1974). Accordingly, Gilead's claim for "reputational harm" damages, on its face, lies beyond this Court's jurisdiction. Dkt. No. 1 at 32 (¶ 117).

Moreover, based on its pleadings and its public statement that Gilead "has suffered reputational harm due to the government's inflammatory and selective allegations asserted in the patent infringement lawsuit,"[14] Gilead's pleadings are also akin to allegations of defamatory statements by the Government, which are also barred. *See Locke v. United States*, 151 Ct. Cl. 262, 269–70 (Ct. Cl. 1960) (barring a claim for false and defamatory communications by contracting officers that "injured plaintiff's business reputation") (citation omitted). So, Gilead's claim for reputational damages, in both name and substance, is jurisdictionally barred.

E. Gilead's "Reputational Harm" Claim Seeks Consequential Damages

Gilead's "reputational harm" claims also seek consequential damages that are unforeseeable, remote, and speculative. This Court may award only actual damages for breach of contract and only for the natural and probable consequences of the breach asserted. *Lucas*, 25 Ct. Cl. at 310–11 (citation omitted); *see also Nutt v. United States*, 12 Cl. Ct. 345, 353 (Cl. Ct. 1987); *S. La. Grain Servs., Inc. v. United States*, 1 Cl. Ct. 281, 286 n.5 (1982) (loss of business reputation is "too remote and consequential"). Because Gilead's allegations of reputational harm are unforeseeable and consequential, its claim should also be dismissed on that basis.

[14] Ex. 9, *Gilead Statement on Complaint Against Federal Government in The Court of Federal Claims* (April 24, 2020) (available at https://www.gilead.com/news-and-press/company-statements/gilead-statement-on-complaint-against-federal-government-in-the-court-of-federal-claims).

F. Gilead's Claims Are Also Jurisdictionally Barred by 28 U.S.C. § 1500

28 U.S.C. § 1500 precludes the Court of Federal Claims' jurisdiction if a plaintiff has a pending suit in another court "for or in respect to" the same "claim or process," at the time the complaint is filed in this Court. *Keene Corp. v. United States*, 508 U.S. 200, 209 (1993). To determine whether section 1500 applies, a court must determine: "(1) whether there is an earlier-filed 'suit or process' pending in another court, and, if so, (2) whether the claims asserted in the earlier-filed case are 'for or in respect to' the same claim(s) asserted in the later-filed Court of Federal Claims action." *Res. Invs., Inc. v. United States*, 785 F.3d 660, 664 (Fed. Cir. 2015) (quoting *Brandt v. United States*, 710 F.3d 1369, 1374 (Fed. Cir. 2013)). "'Two suits are for or in respect to the same claim . . . if they are based on substantially the same operative facts, regardless of the relief sought in each suit,' or the legal theories asserted." *Petro-Hunt, L.L.C. v. United States*, 862 F.3d 1370, 1381–82 (Fed. Cir. 2017) (citing *United States v. Tohono O'odham Nation*, 563 U.S. 307, 317 (2011); *Keene*, 508 U.S. at 212).

"[T]he statute [is not] to be rendered useless by a narrow concept of identity." *Trusted Integration, Inc. v. United States*, 659 F.3d 1159, 1164–65 (Fed. Cir. 2011) (quotation omitted). Rather, section 1500 "suggests a broad prohibition," informed by the principles of *res judicata*. *Tohono*, 563 U.S. at 307, 316. Where the operative factual allegations are "nearly identical," section 1500 operates to remove jurisdiction from this Court. *Petro-Hunt*, 862 F.3d at 1381–82 (citations omitted).

1. Gilead's Unclean Hands Defenses Should Be Evaluated on the Same Grounds as its Earlier Counterclaims

Gilead's Complaint addresses section 1500 only by alleging that its "unclean hands defense does not bar this Court's jurisdiction under 28 U.S.C. § 1500." Dkt. No. 1 at 7 (¶ 27) (emphasis added). Gilead does not mention that it had earlier asserted four counterclaims based on the same

"unclean hands" allegations in the Delaware Litigation, which it dropped a few weeks prior to filing suit in this Court. Ex. 2 at 89 (¶ 89), 91 (¶ 107), 93 (¶ 125), 95 (¶ 143). To the extent that Gilead seeks to avoid section 1500's requirement of a "claim or process" simply by reframing its counterclaims as an affirmative defense, that argument elevates legal form over substance.

This position is consistent with precedent holding that "the principles of preclusion law [are] embodied in" section 1500. *Tohono*, 563 U.S.at 316; *see also Trusted Integration*, 659 F.3d at 1164. *Res judicata* applies equally to affirmative defenses as it does to claims. It specifically precludes the assertion of all "claims or defenses that, through diligence, should have been litigated in the prior suit but were not." *Weaver v. Tex. Cap. Bank N.A.*, 660 F.3d 900, 906 (5th Cir. 2011) (citations omitted). Therefore, because Gilead has asserted the defense of unclean hands (based on the present breach of contract allegations) in the currently-pending Delaware Litigation,[16] section 1500 bars Gilead's Complaint in this Court. *See Christopher Village, LP v. United States*, 53 Fed. Cl. 182, 188 (2002).

2. Gilead's Pleadings are "Nearly Identical" and Address the Same Operative Facts

When the test of section 1500 is applied, it is not disputed that the Delaware litigation is (1) an earlier-filed suit in another court that (2) was pending at time Gilead filed its Complaint. Gilead's Complaint also alleges the same facts alleged in its first amended Answer and Counterclaims in the Delaware Litigation, which was pending at the time Gilead filed suit in this Court. Accordingly, there is "an earlier filed suit or process pending in another court" that is "for

[16] As previously stated, that affirmative defense is the subject of a pending motion to strike by the Government. If granted, no breach of contract allegations would remain in Gilead's defenses in the Delaware Litigation.

or in respect to the same claim(s) asserted in the later-filed Court of Federal Claims action." *Res. Invs.*, 785 F.3d at 664.

The latter conclusion applies equally to both of Gilead's grounds for breach of contract in this Court. First, Gilead pleads that "beginning in 2004, Gilead and CDC entered into numerous MTAs, pursuant to which Gilead agreed to provide CDC with significant quantities of Gilead compounds free of charge." Dkt. No. 1 at 2 (¶ 6). It further alleges that under the MTAs, the Government agreed to "promptly notify" Gilead of any inventions, and in turn, to give "serious and reasonable consideration" to a Gilead request for a license to those inventions. *Id.* Gilead pled the same facts in the District of Delaware. Ex. 3 at 69 (¶¶ 8–10). Gilead further pleads that it "repeatedly delivered the compounds that CDC requested in a timely manner . . . . [and] CDC utilized the compounds that Gilead provided . . . ." Dkt. No. 1 at 2 (¶ 7). Gilead pled the same facts in the District of Delaware. Ex. 3 at 69 (¶ 11).

Regarding the second ground, Gilead alleges that the parties "also entered into a Clinical Trial Agreement with an effective date of November 18, 2004. This agreement set forth the terms under which Gilead would provide antiviral products free of charge for a clinical trial about HIV prevention in Botswana." Dkt. No. 1 at 3 (¶¶ 8–9). Gilead then quotes the portion of the CTA stating that "'CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial.'" *Id.* Gilead pled the same facts in the Delaware Litigation. Ex. 3 at 75 (¶ 37).

Gilead also that pled the Government breached its obligations under the MTAs and CTA before both this Court and the District of Delaware. *Compare* Dkt. No. 1 at 3 (¶ 10) ("The Government breached its obligations under both the MTAs and the CTA.") *with* Ex. 3 at 68 (¶ 6) ("the Government has demonstrated unclean hands because it breached its obligations under at

least four Material Transfer Agreements . . . [the Government's] applications for the HHS Patents violated the clear terms of a Clinical Trial Agreement with GSI.").

Gilead's claims of contractual breaches before the District Court in Delaware and this Court unquestionably revolve around the same operative facts, which are identically pled:

> In spite of the express terms of the MTAs requiring CDC to "promptly notify" Gilead of any claimed "Inventions" arising out of the research conducted under the MTAs and the clear terms of the CTA expressly providing that "CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial," CDC not only filed patent applications seeking patent protection for purported "Inventions" derived from the use of the compounds Gilead supplied under the MTAs and CTA, but also failed to disclose to Gilead the purported invention(s) claimed in the '811 Provisional and in the applications that eventually issued as the HHS Patents.

Dkt. No. 1 at 4 (¶ 13); Ex. 3 at 75–76 (¶ 38). Indeed, Gilead appears to have copied *verbatim* its affirmative defense from Delaware into its Complaint, which should be barred by 28 U.S.C. § 1500 on that basis.

G. Gilead Fails to Plead Contract Claims for Which Relief May be Granted

Apart from jurisdictional requirements, Rule 8 requires Gilead's Complaint to "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation omitted). A claim has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 678 (citing *Bell Atl. Corp.*, 550 U.S. at 556). Thus a complaint must contain "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id*. (citing *Twombly*, 550 U.S. at 555)). Otherwise, a complaint can be dismissed (in whole or in part) under Rule 12(b)(6).

1. To Plead a Breach of Contract, Gilead Must Plead Damages and Requisite Causation

The requirements of a well-pleaded complaint apply to the demand for relief as well. In contract cases, a well-pleaded complaint must allege, *inter alia*, (1) actual (or compensatory) damages and (2) that these damages would not have occurred "but for" the alleged breach(es). *See Hughes Commc'ns Galaxy, Inc. v. United States*, 271 F.3d 1060, 1066 (Fed. Cir. 2001); *see also San Carlos Irrigation & Drainage Dist. v. United States*, 111 F.3d 1557, 1562–63 (Fed. Cir. 1997).

Gilead alleges that it "has suffered, and will continue to suffer, damages because of the Government's breaches of the MTAs and the CTA." Dkt. No. 1 at 4 (¶ 14). It specifies the monetary damages as (1) attorneys' fees and (2) reputational harm. But Gilead fails to plead either with sufficient specificity to meet the mandated Rule 8 standards.[17]

2. Gilead Fails to Adequately Plead Reputational "Harm"

With respect to reputational harm, Gilead pleads little more than that it "has suffered" such harm. *See, e.g.*, Dkt. No. 1 at 32 (¶ 117). It pleads no facts supporting this statement and makes no specific allegations of how its corporate reputation has been harmed. Accordingly, the Complaint contains the sort of naked assertions and unadorned, the-defendant-unlawfully-harmed-me accusations that the Supreme Court has deemed insufficient. *Iqbal*, 556 U.S. at 678. Gilead's conclusory statements regarding reputational harm damages therefore fail to properly state a claim. *See id.* ("Labels and conclusions" or "a formulaic recitation of the elements of a cause of action"

[17] Gilead does plead that if "the HHS Patents are ultimately upheld," it "is also entitled to monetary damages in the amount of the difference between the royalties to which the Government claims it is entitled and the cost, on commercially reasonable terms, of a nonexclusive license to the purported invention(s)." Dkt. No. 1 at 6 (¶ 22). But Gilead never revisits this relief in its breach of contract allegations, nor mentions it in the prayer for relief. *See* Dkt. No. 1 at 36–37.

do not suffice to state a claim) (internal quotations and citations omitted); *see also Toon v. United States*, 96 Fed. Cl. 288, 296 (2010).

3. Gilead Fails to Adequately Plead "But For" Causation

Gilead's pleadings also make clear that it cannot plead the requisite "but for" causation for either of its damages theories. First, Gilead pleads that its reputational harm is "due to the Delaware litigation," not the claimed breach of contract. *See e.g.*, Dkt. No. 1 at 32 (¶ 117). Though Gilead may argue that the required "but for" causation is somehow implied, such "[c]onclusory allegations of law and unwarranted inferences of fact do not suffice to support a claim." *Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998). Accordingly, Gilead's claims for reputational damages should be dismissed for lack of properly alleged causation.

Second, Gilead pleads that the attorneys' fees it seeks are a "a direct and proximate result of the Government's delay in notifying Gilead of its purported invention and of the issuance of the '509 Patent on June 2, 2015, and after the Government's demands that Gilead license the '509 Patent beginning on March 11, 2016 . . ." *E.g.*, Dkt. No. 1 at 32 (¶ 117) (emphases added). Simply put, Gilead pleads that its alleged harm depended on not just the alleged breach, but also the (1) subsequent issuance of the HHS Patents by the PTO and (2) the decision of the Government to act to protect federal intellectual property.[18] This heavily conditional causation demonstrates how the breach is not the "but for" cause of the alleged injury. Gilead's claim of attorneys' fees should also be dismissed under Rule 12(b)(6).

[18] To the extent that Gilead responds that the breaches caused the issuance of the patents and/or the subsequent enforcement, neither causal chain is sufficiently pled, presenting a further ground of inadequacy.

4. HHS Patent Applications Predate the CTA, Rendering It Inapplicable

As discussed, *supra* Part II.C, Gilead did not provide dual-regimen study drugs (Truvada®) under the CTA until after CDC filed its original patent application and published its groundbreaking research. In turn, the CTA's obligation to "not seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial" does not apply to the inventions covered by or claiming priority to the HHS Patents.

Gilead pleads that "Gilead and the Government, acting through CDC, [] entered into a Clinical Trial Agreement with an effective date of November 18, 2004." Dkt. No. 1 at 3 (¶ 8). But as discussed, *supra* Part II.C, the Botswana protocol was changed, and Gilead began providing Truvada® (FTC/TDF) as a study drug under the CTA only after CDC's invention had occurred and after CDC had sought patent protection. The Botswana researchers, in fact, credited the earlier CDC research for informing its new "TDF2" protocol. Dkt. No. 1-15 at 2.

Gilead pleads that "decisions made during prosecution of the '811 Provisional, the '547 Application, and the HHS Patents [] derive from the trials described in the original CTA and its subsequent amendments." Dkt. No. 1 at 22 (¶ 78). But "courts have held that the filing of the patent application itself represents the constructive reduction of practice of the claimed invention, thus representing constructive possession of that which is claimed." *Custom Metalcraft v. Hoover Materials Handling Grp.*, No. 05-3174-CV-S-RED, 2007 U.S. Dist. LEXIS 111218, at *12 (W.D. Mo. Jan. 30, 2007) (citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998)). Federal Circuit law has long required that an "applicant must [] convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is . . . whatever is now claimed." *Vas-Cath Inc. v. Sakharam D. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991) (emphasis added). Because all four HHS Patents claim priority to the '811 Provisional, which was filed well before Gilead provided Truvada® for the TDF2 study, all

inventions in the HHS Patents were necessarily in the Government's possession before the first CTA amendment.

Accordingly, Gilead cannot plausibly claim that the HHS Patents were "derive[d] from" the TDF2 study. And thus the original CTA's obligation does not apply to the HHS Patents. Gilead has failed to, and cannot, state a claim based on the original or amended CTA for which relief can be granted.

CONCLUSION

For the reasons set forth above, this Court should dismiss Gilead's Complaint, in its entirety, for lack of jurisdiction under RCFC 12(b)(1) or for failure to state proper damages claims upon which relief may be granted under RCFC 12(b)(6).

Respectfully submitted,

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